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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/333,256	06/15/99	ENGEL J	PM26021897/2

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EXAMINER	
TRAN,S	
ART UNIT	**PAPER NUMBER**
1615	3

DATE MAILED: 03/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/333,256	Applicant(s) Engel et al.
	Examiner Susan Tran	Group Art Unit 1615

☒ Responsive to communication(s) filed on *Sep 9, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99.

Abstract objections

1. The abstract of the disclosure is objected to because of the following informality:

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet with in the range of 50 to 250 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claim 4 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim 1 to 3. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. It is suggest to amend claim recite "as claimed in any one of claim 1 to 3".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "comprising in the core cyclophosphamide, one or more fillers, one or more dry binders but no preswollen starch, flow regulators and lubricants" is confusing. It

is suggest to amend claim to recite "comprising in the core cyclophosphamide, one or more fillers, flow regulators, lubricants, and one or more dry binders but no preswollen starch".

Claim 2 is indefinite in the use of the phrase "comprising in the core as a filler lactose monohydrate, D-mannitol or $CaHPO_4$, nonpreswollen cornstarch or microfine cellulose as a dry binder, highly disperse silica as a flow regulator and magnesium stearate, stearic acid, glycerol palmitostearate, polyethylene glycol, talc or glycerol monobeherate as a lubricant". It is suggest to amend claim to recite "comprising in the core as a filler lactose monohydrate, D-mannitol or $CaHPO_4$, as a dry binder nonpreswollen cornstarch or microfine cellulose, as a flow regulator highly disperse silica, and as a lubricant magnesium stearate, stearic acid, glycerol palmitostearate, polyethylene glycol, talc or glycerol monobeherate".

Claim 4 is indefinite in the use of the term "preferably and particularly" since they are considered to be a range within a range. It is not clear if the range is limiting or just exemplary. Correction is requested by the elimination of one of the range.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. USPN 5,905,149 ('149).

Battistini discloses a film-coated pharmaceutical tablet composition comprising corn starch, silica, talc, magnesium stearate, polyethylene glycols, mannitol, and cyclophosphamide (column 11, line 12 through column 12, lines 1-20). The amount of lactose monohydrate, nonpreswollen cornstarch, talc, silica, and magnesium stearate are clearly inherent since the same results accrue from the use of the reference film-coated pharmaceutical tablet composition containing the ingredient cyclophosphamide.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al. ('149), in view of Eugster et al. USPN 5,593,691 ('691).

Battistini is relied upon for the reasons stated above. The reference is silence in the teaching of the amount of the filler, dry binder, flow regulator, and lubricant.

Eugster teaches a coated tablet composition comprising cyclophosphamide (column 11, lines 54-56), and pharmaceutical excipient comprising calcium phosphate as a filler, corn starch as a binder, polyethylene glycol as a flow-control, and talc or magnesium stearate as a glidant

(column 21, line 32 through column 22, lines 1-11). The amount of the pharmaceutical acceptable excipient is taught in column 32, lines 30-35.

Absent unexpected results, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the coated tablet composition of Battistini with the pharmaceutical acceptable excipient amount teaches by Eugster to obtain the claimed invention because the cited references teach the advantageous results obtained in the use of cyclophosphamide with the pharmaceutical excipient in a coated tablet composition.

6. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feige et al. USPN 5,229,405 ('405), in view of Hoy et al. USPN 5,208,030 ('030).

Feige teaches coated tablet composition comprising cyclophosphamide (column 5, lines 28-30), calcium phosphate as a filler, starch as a binder, silica as a flow conditioner, and magnesium stearate as a lubricant (column 8, lines 5-30).

Feige fails to specifically teach the amount of the excipient and microfine cellulose as a binder.

Hoy teaches a composition for coated tablet dosage form comprising microfine cellulose as a binder, lactose monohydrate as a filler, and which is also a tableting auxiliary, and silica as a flow improving agent (column 2, lines 48-68). The amount of the filler, binder and flow agent is taught in column 8, lines 15-30.

The examiner notes that the amount of the microfine cellulose of the cited reference is more than the claimed amount. However, it would have been prima facie obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of microfine cellulose as a binder, because the skill artisan would have been motivated to prepare a coated pharmaceutical tablet with the use of microfine cellulose for easy swallow, or after being dispersed in water can still be drunk.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
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